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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/597,803	04/13/2007	Robert Tridgett	3063.002US1	6534	
21186 7590 04/30/2012 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938		EXAMINER			
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MIINNEAPOLI	5, IVIN 55402		3063.002US1 6534 EXAMINER RICCI, CRAIG D ART UNIT PAPER NUMBER 1628 NOTIFICATION DATE DELIVERY MODE	PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)				
	10/597,803	TRIDGETT ET AL.				
Office Action Summary	Examiner	Art Unit				
	CRAIG RICCI	1628				
 The MAILING DATE of this communication app Period for Reply 	ears on the cover sheet with the c	orrespondence ad	dress			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be time rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this co D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 26 Ap	oril 2010					
·= · ·	action is non-final.					
3) An election was made by the applicant in response		set forth during the	e interview on			
; the restriction requirement and election have been incorporated into this action.						
4) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under E	•					
Disposition of Claims	•					
5) Claim(s) <u>35-71</u> is/are pending in the application	1.					
5a) Of the above claim(s) <u>37,40,41,43-46,50-57</u>		rom consideratior	1.			
6) Claim(s) is/are allowed.						
7) Claim(s) <u>35,36,38,39,42,47-49,58-60,62 and 67-71</u> is/are rejected.						
8) Claim(s) is/are objected to.						
Application Papers						
10) ☐ The specification is objected to by the Examiner.						
11) The drawing(s) filed on is/are: a) acce		Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correcti	• • • • • • • • • • • • • • • • • • • •	, ,	FR 1.121(d).			
12) The oath or declaration is objected to by the Ex						
Priority under 35 U.S.C. § 119						
13) Acknowledgment is made of a claim for foreign	priority under 35 LLS C & 119(a)	-(d) or (f)				
a) ☐ All b) ☐ Some * c) ☐ None of:	priority under do d.e.d. g 110(a)	(4) 01 (1).				
1. ☐ Certified copies of the priority documents	s have been received					
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2)	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:					
S Patent and Trademark Office						

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/26/10, 8/23/10, 9/09/10, 3/09/11, 10/23/11.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/26/2010 has been entered.

Response to Arguments

2. Applicant's arguments, filed 4/26/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 58-60, 62 and 67-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claim 58 is drawn to the 3,11b-cis-dihydrotetrabenazine or salt thereof according to claim 35 which consists of greater than 90% 3,11b-cis-dihydrotetrabenazine, or a salt thereof. It is unclear how 3,11b-cis-dihydrotetrabenazine can consist of less than 100% of 3,11b-cis-dihydrotetrabenazine. Accordingly, instant claim 58 is rejected since the skilled artisan would

not be reasonably apprised of what constitutes 3,11b-cis-dihydrotetrabenazine consisting of, for example, 91% 3,11b-cis-dihydrotetrabenazine. The skilled artisan would not be able to ascertain the metes and bounds of the claim.

- 6. For the same reasons, claims 59-60, 62 and 67-68 are rejected. It is unclear and one of ordinary skill in the art would not be able to ascertain the metes and bounds of a composition comprising 3,11b-cis-dihydrotetrabenazine or a salt thereof wherein said 3,11b-cis-dihydrotetrabenazine consists of less than 100% 3,11b-cis-dihydrotetrabenazine or a salt thereof.
- 7. Applicant traverses. In particular, Applicant argues that "claim 58 is drawn to the 3,11b-cis-dihydrotetrabenazine or a salt thereof according to claim 35, which consists of greater than 90% 3,11b-cis-dihydrotetrabenazine, or a salt thereof. Claim 58 depends from claim 35 [wherein] Applicant submits that claim 35 is drawn to 3,11b-cis-dihydrotetrabenazine (or salts thereof) in all amounts, and/or any amount. Thus, if the 3,11b-cis-dihydrotetrabenazine (or salts thereof) was present in 10%, 30%, 50% or some other percentage, whether in solution or dry mixture (or some other form), claim 35 would still embrace that solution or dry mixture (or that other form)" (Applicant Arguments, Page 10).
- 8. In response to Applicant's argument, Applicant is directed to the claim language of claim 35, which recites only "3,11b-cis-dihydrotetrabenazine or a salt thereof". Claim 35 is in no way directed to a solution or dry mixture or some other form of composition comprising 3,11b-cis-dihydrotetrabenazine in all amounts and/or any amount as asserted by Applicant. The claim is directed exclusively to a compound and it is unclear, as previously stated, how the *compound* of claim 35 can consist of less than 100% of the *compound* itself. The composition claims are rejected for the same reason: while a *composition* can comprise less than 100% of a compound,

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the instant claims are drawn to compositions comprising a *compound* wherein the *compound* consists of greater than 90% of the *compound* itself. Once again, it is unclear how any composition can comprise a *compound* wherein the *compound* consists of less than 100% of itself.

9. For all the foregoing reasons, the claims are maintained rejected.

Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claims 35, 42 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kilbourn et al* (cited in a previous Action) as evidenced by *Williams et al* (cited in a previous Action).
- 13. As discussed in the previous Action mailed on 10/27/2009, instant claim 35 is drawn to **3,11b-cis-dihydrotetrabenazine** or a salt thereof, more specifically in the form of a **2S,3S,11bR**

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isomer having the following formula

as elected

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by Applicant, which reads on **claims 35 and 42**. The elected compound species was previously rejected and that rejection is being reiterated in large part as follows:

- 14. **Dihydrotetrabenazine** is well known in the art and, as disclosed by *Kilbourn et al*, "contains three asymmetric carbon centers (C-2, C-3 and C-11b). The two isomers at the C-2 carbon can be easily resolved by column chromatography and are termed α and β -dihydrotetrabenazine... For α dihydrotetrabenazine, with two asymmetric centers, there are four possible isomers" (Page 249, Column 2).
- 15. Accordingly, one of ordinary skill in the art would understand that β -dihydrotetrabenazine similarly contains two asymmetric centers and thus also has four possible isomers. As such, one of ordinary skill in the art would recognize that dihydrotetrabenazine (i.e., α and β -dihydrotetrabenazine) has eight possible isomers which can be immediately envisaged as (1) 2S,3S,11bS, (2) 2S,3S,11bB, (3) 2S,3S,11bS, (4) 2S,3S,11bB, (5) 2R,3S,11bS, (6) 2R,3S,11bB, (7) 2R,3S,11bS, and (8) 2R,3R,11bR (Applicant's elected species in bold, 3,11b-cis isomers underlined).
- 16. However, *Kilbourn et al* do not explicitly disclose Applicant's elected species.
- 17. Yet, as recognized by *In re Schauman*, 572 F.2d 312 (CCPA 1978), claims to a species (such as 3,11b-*cis*-dihydrotetrabenazine in the form of a 2*S*,3*S*,11b*R* isomer) are anticipated

where the prior art teaches a genus embracing a limited number of members closely related to each other in structure and the properties possessed by the genus of the prior art is that disclosed for the claimed species. Significantly, a genus embracing about 20 compounds has been considered sufficiently limited such that each member of the genus can be at once envisaged. *In re Petering*, 301 F.2d 676 (CCPA 1962). In the instant case, the genus embraced by dihydrotetrabenazine comprises just eight members and the properties of the genus taught by the prior art are those disclosed for the claimed species (i.e., inhibition of the human vesicular monoamine transporter isoform 2 (hVMAT2), see instant Specification, Page 1, Lines 15-16 and Page 4, Lines 22-23).

- 18. Furthermore, it is well known that a single isomer is often therapeutically superior to the racemic mixture and to the other isomers. The potential advantages include (1) improved therapeutic index through increased potency and selectivity and decreased side-effects; (2) improved onset and duration of effect; and (3) decreased propensity for drug-drug interactions. Indeed, as taught by *Williams et al*, discussing compounds that are combinations of isomers: "when introduced into an asymmetric, or chiral, environment, such as the human body, enantiomers will display different physical chemical properties producing significant differences in their pharmacokinetic and pharmacodynamic behavior. Such differences can result in adverse side effects or toxicity dues to one of the isomers or the isomers may exhibit significant differences in absorption, serum protein binding, and metabolism" (Page 50, Column 1).
- 19. Accordingly, in view of all of the foregoing, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce the 2S,3S,11bR isomer as recited by the instant claims. Considering that the genus embraced by dihydrotetrabenazine

comprises just eight members, the skilled artisan would have immediately envisaged each member, including 3,11b-cis-dihydrotetrabenazine in the form of a 2S,3S,11bR isomer. Furthermore, the skilled artisan would have predicted that the 2S,3S,11bR isomer would likely possess properties similar to those exhibited by the racemic mixture and trans-isomers disclosed by *Kilbourn et al.*, and potentially superior properties in view of *Williams et al.* As such, the skilled artisan would have been motivated to produce the 2S,3S,11bR isomer in order to determine whether the 2S,3S,11bR isomer does indeed exhibit superior properties (e.g., increased potency and selectivity, decreased side-effects, improved onset and duration, reduced drug-drug interactions, etc). "A known compound may suggest its analogs or isomers, either geometic isomers (cis v. trans) or position isomers (e.g., ortho v. para)" *In re Deuel*, 51 F.3d 1552, 34 USPQ 2d 1210, 1214 (Fed Cir 1995).

- 20. Accordingly, instant claims 35 and 42 are rejected as *prima facie* obvious.
- 21. Applicant traverses on a variety of grounds numbered 1-6 on Pages 13-14 of Applicant's Arguments (and further contained on Pages 14-19 of Applicant's Arguments). As to Arguments 1-4 and 6, no additional response is provided herein since those arguments were addressed in the previous Action in Paragraphs 15-17.
- 22. As to Argument 5, Applicant asserts that "[t]he compounds of the invention exhibit unexpected benefits and properties that are not predictable from the prior art disclosures related to the known trans-dihydrotetrabenazine isomers. Evidence of the surprising properties of the compounds of the instant invention is set forth in the patent specification and in a Declaration by Phil Nichols, submitted herewith" (Applicant Arguments, Page 14).

23. In response to Applicant's assertion of unexpected results, the following is provided: It is well settled that a showing of unexpected results is generally sufficient to overcome a prima facie case of obviousness. In re Albrecht, 514 F.2d 1389 (CCPA 1975). However, as recognized by the court in *In re Schulze*, 346 F.2d 600 (CCPA 1965), mere arguments are not sufficient to demonstrate unexpected results. Rather, unexpected results must be established by factual evidence by comparing the claimed invention with that of the closest prior art. In re Burckel, 592 F.2d 1175 (CCPA 1979). As discussed by the court in *In re De Blauwe*, 736 F.2d 699 (Fed. Cir. 1994), "the absence of tests comparing [Applicant's claimed invention] with those of the closest prior art... constitute mere argument". In the instant case, Applicant has NOT compared the claimed invention with that of the closest prior art and provided factual evidence which establishes unexpected results of the claimed invention. Rather, Applicant compared the instantly elected cis-isomer (as well as non-elected cis-isomers) with tetrabenazine (see Declaration of Phil Nichols (entire document) and Applicant Arguments, Pages 16-17) and contend that the instant isomers lack the sedative properties and DAT activity of **tetrabenazine**. However, the closest prior art is racemic dihydrotetrabenazine and trans-isomers of dihydrotetrabenazine (as disclosed by Kilbourn et al). Although Applicant contends that "the active metabolite of tetrabenazine, trans-dihydrotetrabenazine is responsible for" the sedative effects of tetrabenazine (and, it is assumed, the DAT activity of tetrabenazine), Applicant has provided no evidence to support this contention. Rather, Applicant references "an article by Brossi et al" and, in particular, page 5 of the Translation (Applicant Arguments, Page 17 and footnote 4). Yet, no Translation is provided. Applicant further references US 2,843,591 for the proposition that **dihydrotetrabenazine** compounds have sedative properties.

2,843,591 identifies **dihydrotetrabenazine** compounds and states the disclosed compounds have sedative properties (Column 2, Line 69), yet there is no data to determine the degree of sedation provided by the compounds so as to conclude that the instantly elected species is unexpectedly superior (note that, based on Applicant's data, that the instantly claimed cis-isomers have sedative properties as well (Nichols Declaration, Items 6-8)). Since no comparisons of the instantly elected cis-isomer (or non-elected cis-isomers) with the closest prior art have been provided (i.e., **dihydrotetrabenazine** and trans-isomers of **dihydrotetrabenazine**), Applicant's assertions of unexpected results "constitute mere argument" and are not found persuasive.

- 24. Claims **35 and 42** are maintained rejected.
- 25. Claim 58 is drawn to the 3,11b-cis-dihydrotetrabenazine or salt thereof according to claim 35 which consists of greater than 90% 3,11b-cis-dihydrotetrabenazine, or a salt thereof. It is unclear how 3,11b-cis-dihydrotetrabenazine can consist of less than 100% of 3,11b-cis-dihydrotetrabenazine.
- 26. Accordingly, instant claim 58 is also rejected.
- 27. Claims 36, 38-39, 49, 59-60, 62 and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kilbourn et al* (cited in a previous Action) as applied to claims 35 and 42 above, in view of *Reich et al* (cited in a previous Action).
- 28. Instant claims 36 and 38-39 are drawn to compositions consisting of (claim 36) or comprising (claims 38-39) 3,11b-cis-dihydrotetrabenazine in substantially pure form (claim 36), being substantially free of 3,11b-trans-dihydrotetrabenazine (claim 38) or containing less than 5% of 3,11b-trans-dihydrotetrabenazine (claim 39).

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- 29. As discussed above, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to produce the cis isomer of dihydrotetrabenazine in an effort to identify a compound exhibiting desirable properties such as increased potency and selectivity, decreased side-effects, improved onset and duration, reduced drug-drug interactions, etc as compared to racemic dihydrotetrabenazine or other isomers of dihydrotetrabenazine. Furthermore, it would have been obvious to a person of ordinary skill in the art to formulate the compositions consisting of or comprising the cis isomer wherein the isomer is in substantially pure form as recited by instant claims 36 and 38-39. As disclosed by Reich et al (who teach compositions comprising amino-pyrazole compounds), "[a]s generally understood by those skilled in the art, an optically pure compound having one chiral center (i.e., one asymmetric carbon atom) is one that consists essentially of one of the two possible enantiomers (i.e., is enantiomerically pure), and an optically pure compound having more than one chiral center is one that is both diasteromerically pure and entiomerically pure" (Column 15, Line 62 - Column 16, Line 1). Moreover, Reich et al teach that compounds most preferably are used in a form that is at least 99% of a single isomer (98% entiomeric excess or diastereomeric excess) (Column 16, Lines 7-8). As such, it would have been obvious to a person of ordinary skill in the art to formulate the composition consisting of or comprising the isomer in a substantially pure form (as recited by instant claim 36), being substantially free of the trans isomer (as recited by instant claims 38 and 39).
- 30. As such, claims 36 and 38-39 are rejected as *prima facie* obvious.
- 31. Instant claim 49 and new claims 69- is drawn to a pharmaceutical composition comprising 3,11b-cis-dihydrotetrabenazine or a salt thereof and a pharmaceutically acceptable

carrier (claim 49), wherein the 3,11b-cis-dihydrotetrabenazine is provided in a therapeutically useful amount (claim 69), which does not inhibit DAT (claim 70) and which is not sedating (claim 71).

- 32. As discussed above, *Kilbourn et al* teach pharmaceutical compositions comprising a *trans* dihydrotetrabenazine isomer strongly binds VMAT2 (entire document). Accordingly, the skilled artisan would have been motivated to formulate pharmaceutical compositions comprising the 2S,3S,11bR cis isomer to determine whether it can bind VMAT2 with increased potency and selectivity, decreased side-effects, improved onset and duration, reduced drug-drug interactions, and so on. To do so, the skilled artisan would have including a therapeutically useful amount of 3,11b-cis-dihydrotetrabenazine. Although *Kilbourn et al* do not explicitly teach the inclusion of a pharmaceutically acceptable carrier, *Kilbourn et al* disclose that the pharmaceutical compositions "were injected via the tail vain" (Page 250, Column 2). Since it is unclear how an injectable composition could not include a pharmaceutically acceptable carrier, it is asserted that, absent evidence to the contrary, the composition of *Kilbourn et al* necessarily includes a pharmaceutically acceptable carrier.
- 33. Accordingly, claims 49 and 69 are rejected as *prima facie* obvious. Moreover, it is asserted, absent evidence to the contrary, that the prima facie obvious composition of claims 49 and 69 would necessarily not inhibit DAT nor be sedating, as recited by claims 70-71.
- 34. Claims 59-60 and 62 are drawn to a composition comprising 3,11b-cis-dihydrotetrabenazine and a pharmaceutically acceptable carrier, wherein the 3,11b-cis-dihydrotetrabenazine, or salt thereof, consists of greater than 90% 3,11b-cis-dihydrotetrabenazine, or a salt thereof. As discussed above, the prior art teaches compositions

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comprising 3,11b-cis-dihydrotetrabenazine and a pharmaceutically acceptable excipient. Additionally, it is unclear how 3,11b-cis-dihydrotetrabenazine can consist of less than 100% of 3,11b-cis-dihydrotetrabenazine. As such, the compositions comprising 3,11b-cis-dihydrotetrabenazine and a pharmaceutically acceptable carrier necessarily provide a composition wherein said 3,11b-cis-dihydrotetrabenazine, or a salt thereof, consists of greater than 90% 3,11b-cis-dihydrotetrabenazine, or a salt thereof.

- 35. Accordingly, claims 59-60 and 62 are rejected as *prima facie* obvious.
- 36. Applicants assert some of the same arguments as discussed above regarding claims 35 and 42 and which are not considered persuasive for the reasons discussed above. The rejection of claims is maintained.
- 37. Claims 47-48 and 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kilbourn et al* (cited in a previous Action) as applied to claims 35 and 42 above in view of *Berge et al* (cited in a previous Action).
- 38. Instant claims 47-48 are drawn to the compound of claim 35 in the form of an acid addition salt (claim 47), more specifically wherein the salt is a methane sulphonate salt (claim 48). As taught by *Berge et al*, "[t]he chemical, biological, physical, and economic characteristics of medicinal agents can be manipulated and, hence, often optimized by conversion to a salt form" (Page 1, Column 1). More specifically, *Berge et al* disclose that methanesulfonic acid is a potentially useful salt form of pharmaceutical agents (Page 5, Table III). Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate the isomer as a mesylate salt. The skilled artisan would have been motivated to do in

order to optimize the chemical, biological, physical and economic characteristics of the compound in view of *Berge et al*.

39. Applicants traverse on the grounds that formulating salts of a compound is unpredictable in view of *Berge et al* (Applicant Argument, Page 22). Yet, as discussed by the court in *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988) obviousness does not require absolute predictability of success, only a reasonable expectation of success. Under the instant circumstances, an expectation of success would have been reasonable. That is, it would have been reasonable to expect that the instantly elected compound could be formulated as a methane sulphonate salt for inclusion in a composition, and it would have been obvious to try to do so with a reasonable expectation of success. Accordingly, Applicants' argument is not found persuasive.

40. Claims 67-68 are drawn to the composition of claims 59 and 67, respectively, In the form of an acid addition salt, more specifically a methane sulphonate salt. Thus, for the same reasons as discussed regarding instant claim 47-48, new claims 67-68 are also rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/CRAIG RICCI/ Examiner, Art Unit 1628